

## **REMARKS**

### **I. Overview**

Claims 1-21 are pending. The Examiner rejected claims 1 and 5-9 on the ground of nonstatutory obviousness-type double patenting. Claims 12-21 were withdrawn from consideration pursuant to a Restriction Requirement traversed by the Applicants.

### **II. Nonstatutory Obviousness-Type Double Patenting**

The Examiner states that claims 1 and 5-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 16 of U.S. Patent No. 6,509,444 ("the '444 Patent'") in view of Hirai et al. (U.S. Patent No. 5,216,127). The Examiner also states that the '444 Patent teaches a method of separating or isolating a serum amyloid A (SAA) protein having sequence ID No. 1, from a colostrum sample of mammal, but fails to teach a step of measuring the presence or amount of said SAA protein and performing an ELISA assay.

The Examiner states that Hirai teaches performing an ELISA assay to detect SAA protein in any fluid component originated in a living body, therefore making it obvious to one of ordinary skill in the art to detect or measure the presence or amount of SAA protein in a sample as taught by Hirai, as a sequential step in the method of the '444 Patent since a detection step must be performed in order to confirm that there is any SAA being separated in the method of the '444 Patent.

The Examiner further states that a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual rejection based on a nonstatutory double patenting ground provided that the conflicting application or patent either is shown to be

commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Applicants respectfully submit that the nonstatutory obviousness-type double patenting rejecting of claims 1 and 5-9 is improper according to MPEP 804, defining nonstatutory obviousness-type double patenting. Specifically, there must be a **claim to claim** comparison between the application and a patent. See General Foods Corp. v. Studiengesellschaft Kohle mbH, 23 USPQ2d 1839, 1846 (Fed. Cir.1992) (when considering whether the invention defined in the claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art).

An obviousness-type double patenting rejection must make clear, "(A) The differences between the inventions **defined by the conflicting claims** – a **claim** in the patent compared to a **claim** in the application; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention **defined in the claim** at issue would have been an obvious variation of the invention **defined in a claim** in the patent." MPEP 804.

The Examiner's rejection on the ground of nonstatutory obviousness-type double patenting over claims 1, 2, 5 and 16 of the '444 Patent in view of Hirai is improper, as it uses the disclosure to attempt to teach the steps missing from the '444 Patent. Specifically, the Examiner states that the '444 Patent fails to teach the step of measuring the presence or amount of said SAA protein and performing an ELISA assay. **The claims of Hirai** also fail to provide such measuring step and performance of an ELISA assay step as required for a nonstatutory obviousness-type double patenting. The claim to claim comparison of the '444 Patent in view of the **claims of Hirai** fall short of teaching the complete method of the present invention.

Even if the Examiner were to consider the disclosure of Hirai in light of the '444 Patent, the combination still fails to teach a person having ordinary skill in the art to develop a method for assaying and utilizing immunologically specific antibodies for Applicant's novel isoform of SAA. Hirai merely patented a method for removing high amounts of SAA from fluids to prevent and/or treat amyloidosis. U.S. Patent No. 5,216,127, col. 1, lines 8-19. Hirai fails to make any reference to inflammatory disorders or diseases. Hirai also fails to make reference to a means or system of detection of serum amyloid proteins. Moreover, Hirai fails to reference any diagnoses, specifically mastitis. The Examiner cites to Hirai, specifically col. 19, line 50, whereby Hirai states the protein concentration was "measured according to ELISA Method" in order to show a decrease in the SAA concentration of a sample.

In light of Hirai's failure to teach a person of ordinary skill in the art to develop a method for assaying and utilizing immunologically specific antibodies for a novel SAA isoform, the "differences between the inventions defined by the conflicting claims – a claim in the patent compared to a claim in the application," as required by MPEP 804, yields no justification for nonstatutory obviousness-type double patenting. The '444 Patent only refers to the presence of SAA (with particular four amino acid peptide sequences TFLK) as are naturally occurring in colostrum. See for example, U.S. Patent No. 6,509,444, col. 5, lines 53-55. The '444 Patent does not refer to or disclose the presence of SAA in milk or its presence as a result of mastitis, or the possibility of the SAA without the presence of TFLK.

### III. No Prior Art

The Examiner states that claims 1-11 are free of prior arts.

### IV. Conclusion

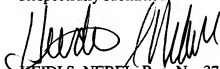
Applicants believe that the present application is now in condition for allowance.

Favorable reconsideration is respectfully requested.

Please consider this a Request for Three Month Extension of Time from January 4, 2008 to April 4, 2008 and charge Deposit Account No. 26-0084 the amount of \$1,050.00 for this extension.

No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



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